

REMARKS

The Written Opinion issued for the above-identified application, stated that Claims 1-29 lacked novelty under PCT Article 33(2) as being anticipated by Haber et al., U.S. 5,253,785; that claims 1, 23, 31-44 and 46 lacked novelty under PCT Article 33(2) as being anticipated by Reilly et al., U.S. 4,677,980. Furthermore, claims 36, 44 and 46 were held to lack novelty under PCT Article 33(2) as being anticipated by Schwebel et al., U.S. 4,089,334, claims 36 and 45 were held to lack novelty under PCT Article 33(2) as being anticipated by Haber et al., U.S. 5,354,284; and claims 36 and 47 were held to lack novelty under PCT Article 33(2) as being anticipated by Tarello et al., U.S. 4,518,384.

Claim 1 has been amended to define a hypodermic injection system as comprising a housing, a container-holding member, latching and release apparatus for releasably latching the holding member to the housing during the injection process and for releasing the holding member and the containers held thereby away from the housing without any physical contact by the user. Neither Haber et al., Reilly et al., or any other reference discloses this feature.

Claim 23 as originally filed, defined a hypodermic injection system for dispensing injectate from at least two cartridges, each of which having a dispensing channel with an exit nozzle, and a plunger for moving through the cartridges to dispense injectate from the cartridge. Claim 23 has been amended to recite that the ram apparatus has a separate ram for each cartridge for moving the plungers in each cartridge simultaneously through each of the cartridges to dispense injectate. Haber et al. only has one exit nozzle and therefore does not anticipate claim 23. Reilly et al. does not disclose a system having a separate ram for moving the plungers in each of the injectate cartridges simultaneously. Reilly et al., has a turret arrangement, where in

each syringe is operated separately, rather than together as defined in claim 23. Reilly et al. does not anticipate claim 23.

Turning next to claim 36, this claim recites a station for re-energizing a hypodermic injection system, where the injection system has a mechanical energy storing apparatus for releasing stored energy when the system makes an injection. Neither Shwebel et al., nor Haber et al., nor Tarello et al. disclose a station for re-energizing a hypodermic injection system whose mechanical energy has been released upon making an injection. Therefore, these references do not anticipate claim 36 or the claims which depend from it.

The Examiner is invited to telephone the undersigned for discussion of any of the issues relating to this application will facilitate this prosecution.

Respectfully submitted,

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D. PETER HOCHBERG
Reg. No. 24,603

D. PETER HOCHBERG CO., L.P.A.
1940 East 6th Street - 6th Floor
Cleveland, Ohio 44114-2294
(216) 771-3800
DPH/kg Enc.

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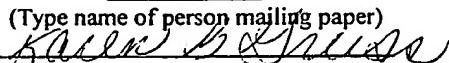
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Karen B. Gruss

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includes a drive mechanism 109 having a hexagonal shape for engaging a corresponding portion of cam axle 83. An enable button 111 is preferably provided so that when a system 1 is inserted in a compartment 103, 105, 107, button 111 is depressed and drive mechanism 109 rotates cam 81 to its loaded or injection ready position. The drive mechanism stops rotating upon the actuation of an internal disable switch which detects the correct amount of rotation. These injector positions could be sensed electronically rather than using the button switches as shown. The hand-held portion, system 1 of Figure 8, is then removed from station 101 for an injection to be made. The system is then reloaded and reset with loading station 101. While injection system 1 in Figure 8 has the same form (less the handle) as shown in Figure 1, in an actual commercial system, it will have a shape that is easily held by the user when giving an injection.

The rear portion of the apparatus shown in Figure 8 is shown in Figure 9. Loading station 101 can be energized using the AC input 113 or a DC input 115. An on/off switch 117 is also provided. The power can be an AC grid or battery, or can use compressed gas, ignitable gas such as butane, hydraulic drive, or manual operation using a hand crank or a foot pedal. Systems 1 shown in Figures 8 and 9 can be easily moved when the injection procedures are completed. Load stations 101 need not be picked up by the health care worker when an injection is given. Loading station 101 and system 1 are only brought together when spring compression is needed, and this could even be done using a long speedometer-type cable connection instead of a direct contact interface as shown in Figures 8 and 9. Even though Figures 8 and 9 show DC and AC power inputs, manual loading is also possible in case of power failure or lack of power at a particular location.

Although Figure 7 shows a spring for each cartridge, a single spring is also possible. Other means for providing pressure for dispensing injectate from the holding members are possible. Other springs besides wire springs could be used as well, including resilient plastic springs, elastomeric springs such as rubber or rubber-like materials, and possibly electro-magnetic fields. Although the cam system shown in Figure 7 has been found to be effective, other means for setting the system would also apply. For example, there could be gearing systems, linear systems, such as those with linear gears, pawl and gear mechanisms, belts, rollers, and the like could be employed.

We claim:

1. A hypodermic injection system comprising:
 - a housing for housing at least one injectate container for an injectate to be injected from the system into a body;
 - 5 a container-holding member for holding the respective injectate containers in position during the injection process for proper injection into the body; and latching and release apparatus for releasably latching said holding member to said housing during the injection process, and for releasing said holding member and the containers held by said holding member from said housing without any
 - 10 physical contact by the user, for non-contaminating disposal after the injection process.
2. A system according to claim 1 wherein said housing houses at least two injectate containers, and said disposable holding member is a structure having openings for holding each of the injectate containers.
3. A system according to claim 2 and further including guard walls around
15 said openings for preventing splashing of the injectate or blood during an injection process.
4. A system according to claim 2 and further including splash guard walls around the outer edge of said container-holding member for preventing the splashing of the injectate during an injection process.
- 20 5. A system according to claim 2 wherein said openings are dimensioned to be press fit with the injectate containers to hold the containers in place.
6. A system according to claim 1 wherein said housing has a front portion, said holding member comprises a front plate, and said latching and release apparatus includes a groove in one of said front plate and said housing and a releasable latching
25 member in the other of said front plate and said housing for releasably entering said groove to latch said front plate to said housing.
7. A system according to claim 2 and further comprising actuatable injectate release device for applying pressure on the respective injectate containers to transmit injectate from said containers for the injection process, and a manually operable trigger
30 device for actuating said injectate release device.
8. A system according to claim 7 wherein said injectate release device

comprises energy storage apparatus for storing energy to be applied to the respective injectate containers, and wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

5 9. A system according to claim 7 wherein said energy storage apparatus comprises at least one spring, a latch for holding the spring in a set condition, and wherein said trigger device comprises a release trigger for releasing said latch to commence the injection process.

10 10. A system according to claim 1 wherein said locking and release apparatus comprises at least one locking member for cooperating with said container-holding member to lock said holding member to said housing, device for releasing said locking member to enable said holding member to be properly positioned on said housing and for activating said locking member to lock said properly positioned holding member to said housing, and an ejection device for ejecting said holding member and the respective 15 containers held by said holding member from said housing.

11. A system according to claim 10 wherein said holding member is a plate with a peripheral edge having a groove, and wherein said locking member enters said groove to lock said plate to said housing, said locking member being removable from said groove to release said plate.

20 12. A hypodermic injection system according to claim 1 and further including at least two injectate containers, said holding member holding said containers in proper position.

25 13. A system according to claim 12 wherein said injectate containers are disposable cartridges, said cartridges each including an injectate channel having injectate nozzles, and wherein said holding member comprises cartridge holders for holding said cartridges for dispensing injectate through said respective channels during the injection process.

30 14. A system according to claim 13 wherein at least one of said cartridges are inactive cartridges having pseudo-channels which are constructed to appear as injectate channels but are non-functional as channels, and said inactive cartridges have externally visible surfaces adjacent said pseudo-channels being coded to appear differently from

corresponding surfaces of the active cartridges.

15. A system according to claim 12 wherein said injectate containers are disposable injectate cartridges, and wherein said holding member comprises cartridge-holding surfaces for holding said cartridges in position to dispense injectate, said 5 injectate cartridges comprising:

an outer wall having an inner wall surface defining an inner chamber;
a plunger engaging said inner wall surface and being movable in said chamber, said plunger defining an injectate-holding portion of said chamber and said chamber having an injectate dispensing end having an exit nozzle, said dispensing end 10 being configured to engage the respective cartridge-holding surfaces, said plunger being drivable into said injectate-holding portion to dispense the injectate through said respective nozzles from said respective cartridges during the injection process.

16. A system according to claim 15 wherein said injectate-holding portion of at least one of said cartridges comprising a rupturable seal dividing said holding portion 15 into two compartments, one of said compartments holding a lyophilized part of an injectate and the other of said compartments holding a predetermined amount of fluid for mixing the components of the injectate.

17. A system according to claim 16 and further including a device for rupturing said seal.

20 18. A system according to claim 1 and further including a biasing device for placing sufficient pressure on said respective containers to force the injectate out of the containers at jet velocity.

19. A system according to claim 12 wherein said injectate containers are six cartridges having injectate exits, said exits being disposed in a rectangular order having 25 three pairs of opposing exits.

20. A system according to claim 12 wherein said injectate containers are cartridges having perforators for piercing the skin of a body and through which injectate flows during an injection process.

21. A system according to claim 1 wherein said housing houses an injectate 30 container, and said disposable holding member is a structure having openings for holding said injectate container.

22. A system according to claim 21 and further including a guard wall around said opening for preventing splashing of the injectate or blood during an injection process.

23. A hypodermic injection system for dispensing injectate, said system
5 comprising: from at least two injectate cartridges, each of said cartridges having a dispensing channel with an exit nozzle, and a plunger for moving through each of the cartridges to dispense injectate from each of the cartridges;

a holding member for holding said respective injectate cartridges with said dispensing channels directed in a common direction;

10 a ram apparatus having separate rams, each movable with respect to one of said cartridges to move the respective plungers for forcing injectate from said cartridges through the dispensing channels and the individual exit nozzle;

a carriage movable from a set position to a dispensing position for moving said ram apparatus at uniform pressures during an injection process;

15 a spring apparatus movable from a cocked position for moving said carriage from the set position to the dispensing position;

a carriage resetting apparatus for moving said carriage from the dispensing position to the set position, and for recocking said spring apparatus, to enable the replacement of the injectate containers; and

20 a releasable latching device for latching said spring apparatus in the cocked position.

24. A system according to claim 23 and further including a housing for housing said holding member, said ram apparatus, said carriage, said spring apparatus, said latching device, said carriage resetting apparatus and said releasable latching device.

25. 25. A system according to claim 24 and further comprising:

a guard plate near said exit orifices for preventing the splashing of injectate from said channels.

26. A system according to claim 23 wherein said carriage resetting apparatus comprises a cam follower operatively connected to said carriage and a cam configured
30 for moving said cam follower and said carriage from the dispensing position to the set position.

27. A system according to claim 23 and further including a housing having a fixed wall for said spring apparatus, and wherein said spring apparatus comprises at least one spring having one end engaged with said fixed wall, and the other end movable to the cocked position when said carriage moves to the set position, said set of springs 5 moving said carriage from the set position to the dispensing position in response to release of said latching device.

28. A system according to claim 27 wherein said spring apparatus further includes movable rods associated with the respective springs for guiding and positioning said springs, said rods having a wall for engaging the other end of the respective springs 10 and being movable in response to movement of said carriage from the dispensing position to the set position for moving said respective springs to the cocked position and wherein said latching device comprises a first latching member extending from said housing and a second latching member on said rods, said first and second latching members having one condition for holding said rods and said respective springs in the 15 cocked position and a second condition for releasing said rods and said respective springs, said respective springs then moving said carriage assembly to the dispensing position.

29. A system according to claim 23 wherein said carriage resetting apparatus comprises a cam follower operatively connected to said carriage and a cam movable 20 from an initial position to a final position and configured for moving said cam follower to move said carriage from the dispensing position to the set position, and a trigger for moving said cam from the final position to the initial position and for releasing said latching device to release said latching device to effect the movement of said spring apparatus from the cocked position to move said carriage from the set position to the 25 dispensing position.

30. A system according to claim 28 and further including a solenoid responsive to sensing signals for releasing said first latching member to unlatch said spring apparatus.

31. A system according to claim 23 wherein said carriage resetting apparatus 30 is operable for moving said carriage from the dispensing position to the set position, and a drive apparatus movable for operating said resetting apparatus, said drive apparatus

being configured to be moved by a correspondingly configured motor driven device.

32. A system according to claim 31 wherein said carriage resetting apparatus is a cam follower for moving said carriage from the dispensing position to the set position, and said drive apparatus is a cam operatively connected to said cam follower,
5 said cam being rotatable by a motor and configured to move said cam follower and said carriage from the dispensing condition to the set position, and said latching device latching said spring apparatus in the cocked position in response to movement of said carriage to the set position.

33. A system according to claim 31 and further including:
10 a housing for housing said holding member, said ram apparatus, said carriage assembly, said spring apparatus, said carriage assembly resetting apparatus, said drive apparatus and said releasable latching device; and
said system further comprising a handle attached to said housing, said handle including:

15 a motor;
a movable tool driven by said motor for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position; and
a power input apparatus for supplying electric power to said motor.

20 34. A system according to claim 31 and further including:
a housing for housing said holding member, said ram apparatus, said carriage, said spring apparatus, said carriage resetting apparatus, said drive apparatus and said releasable latching device; and
a loading station for cooperating with said housing to operate said carriage resetting apparatus, said loading station including a motor and a movable tool for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position.

25 35. A system according to claim 23 and further including a sensing apparatus for emitting a sensing signal to indicate the presence or absence of at least one cartridge held by said holding member, and wherein said releasable latching device operates in
30 response to the presence or absence of the sensing signal.

36. A station for re-energizing a hypodermic injection system, the injection system having a mechanical energy storing apparatus for releasing stored energy when the system makes an injection, the mechanical energy storing apparatus having an input mechanism for cooperating with a re-energizing mechanism, said station comprising:

5 an energy transferring apparatus for transferring energy from an energy source;

 a re-energizing mechanism for transmitting energy from said energy transferring apparatus to the input mechanism of the energy storing apparatus, said re-energizing mechanism cooperating with the input mechanism to effect the transmission
10 of energy from said energy transferring apparatus to the mechanical energy storing apparatus.

37. A station according to claim 1 wherein the injection system has a predetermined external configuration and the input mechanism has a drivable surface for receiving energy to be stored in the energy storing apparatus, and wherein said re-energizing apparatus has a drive surface for cooperating with the drivable surface to re-energize the energy storing apparatus of the injection system.
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38. A station according to claim 37 wherein the input mechanism comprises a cam mounted on an axle and the drivable surface is a surface of the axle, and wherein said drive surface of said re-energizing apparatus is a device for contacting the drivable
20 surface and rotating the axle to rotate the cam.

39. A station according to claim 37 wherein the injection system has a predetermined external configuration, and said station includes at least one nesting apparatus for receiving and supporting the injection system, and wherein said drive surface cooperates with the drivable surface of the injection system to re-energize the
25 energy storing apparatus of the system.

40. A system according to claim 39 wherein the energy storing apparatus of the injection system is at least one spring, and said re-energizing mechanism cocks the spring.

41. A station according to claim 40 wherein the injection system further
30 includes a rotatable cam for operating a device to cock the spring and the drivable surface is connected to the cam, and wherein said drive surface cooperates with the

drivable surface to rotate the cam and cock the spring.

42. A station according to claim 39 wherein the injection system includes apparatus for receiving disposable cartridges holding injectate, and wherein said station further including a supporting device to hold the injection system for reloading the 5 injection system with fresh cartridges containing injectate.

43. A station according to claim 36 wherein said re-energizing mechanism includes a manually operable member for transmitting energy from a person operating said member to the mechanical energy storing apparatus.

44. A station according to claim 36 wherein said re-energizing mechanism 10 includes a compressed gas operable member for transmitting energy from the compressed gas to the mechanical energy storing apparatus.

45. A station according to claim 36 wherein said re-energizing mechanism includes an hydraulically operable member for transmitting energy from the device exerting pressure on the hydraulic fluid to the mechanical energy storing apparatus.

15 46. A station according to claim 36 wherein said re-energizing mechanism includes an ignitable gas operable member for transmitting the ignition energy to the mechanical energy storing apparatus.

47. A station according to claim 36 wherein said re-energizing mechanism includes an electrically operable member for transmitting electrical energy to the 20 mechanical energy storing apparatus.

Abstract of the Invention

A hypodermic system(1) for injecting injectate from at least one injectate container(13), the system having a spring-loaded carriage(57) for moving a plunger(43) through each container(13) to force injectate from the containers(13).

- 5 Apparatus is provided for resetting the spring(s)(61) after completion of an injection process.